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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/586,109

10/31/2006

Eric Allain

10674.204-US

1362

25908 7590 03/04/2010  
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EXAMINER

PAK, YONG D

ART UNIT

PAPER NUMBER

1652

NOTIFICATION DATE

DELIVERY MODE

03/04/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/586,109	<b>Applicant(s)</b> ALLAIN ET AL.	
	<b>Examiner</b> YONG D. PAK	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 52-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 52, 53 and 55-63 is/are rejected.
- 7) ☒ Claim(s) 54 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This application is a 371 of PCT/US05/01147.

The amendment filed on November 2, 2009, canceling claims 35-51 and adding claims 52-63 and amending pages 12, 14, and 23 of the specification, has been entered.

Claims 52-63 are pending and are under consideration.

### ***Response to Arguments***

Applicant's amendment and arguments filed on November 2, 2009, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### ***Objections to the Specification***

In view of the amendment of the specification, the objections to the specification has been **withdrawn**.

### ***Claim Rejections - 35 USC § 112 – 2<sup>nd</sup> paragraph***

In view of the cancellation of claims 41 and 47, the rejection of claims 41 and 47 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly

point out and distinctly claim the subject matter which applicant regards as the invention has been **withdrawn**.

***Claim Rejections - 35 USC § 112- 1<sup>st</sup> paragraph***

In view cancellation of claims 35-49 and 51, the rejection of claims 35-49 and 51 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, has been **withdrawn**.

In view cancellation of claims 35-49 and 51, the rejection of claims 35-49 and 51 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, has been **withdrawn**.

***Claim Rejections - 35 USC § 102***

In view cancellation of claims 35-40, 42- 44, and 50-51, the rejection of claims 35-40, 42- 44, and 50-51 under 35 U.S.C. 102(b), as being anticipated by Nagasaka et al., has been **withdrawn**.

In view cancellation of claims 35-40, 42, 44-47, and 49-51, the rejection of claims 35-40, 42- 44, and 50-51 under 35 U.S.C. 102(b), as being anticipated by Borchert et al., has been **withdrawn**.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 52-53 and 55-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veit et al., Svendsen et al. and Nagasaka et al.

Claims 52-53 and 55-63 are drawn to a method of producing and recovering ethanol from milled starch-containing material obtained from whole grain by simultaneous saccharification and fermentation, wherein said starch-containing material is saccharified with a glucoamylase having at least 9899-% sequence identity to SEQ ID NO:2 at a temperature below the gelatinization temperature of said starch-containing

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material, the sugar concentration is kept at a level below 3 wt %, and said method uses a fungal acid protease and a hybrid enzyme comprising an *Aspergillus niger* acid alpha-amylase catalytic domain (CD) and a carbohydrate-binding module (CBM) from *Aspergillus kawachii* alpha-amylase.

Veit et al. (US 7,244,597 B2 or WO 02/38787 A2 - form PTO-892) discloses a method of producing and recovering ethanol by (1) milling a whole grain, (2) liquefaction of the milled starch-containing material with an alpha-amylase hybrid, and (3) simultaneous saccharification and fermentation of the product from step (2) (Column 1, lines 48-62 of US 7,244,597 or pages 1-2 of WO 02/38787 A2). Step (2) of Veit et al. utilizes alpha-amylase hybrid comprising 445 C-terminal amino acid residue of the *Bacillus licheniformis* alpha-amylase and the 37 N-terminal amino acid residue of the alpha-amylase derived from *Bacillus amyloliquefacien* (Column 9, lines 4-8 of US 7,244,597 or page 11 of WO 02/38787 A2). Step (3) of Veit et al. employs a fungal acid protease (Column 12, lines 9-37 of US 7,244,597 or page 15 of WO 02/38787 A2) and is carried out at a temperature below the initial gelatinization temperature (Column 5, lines 18-67 of US 7,244,597 or pages 6-7 of WO 02/38787 A2).

The difference between the reference of Veit et al. and the instant invention is that the reference of Veit et al. does not use a glucoamylase having at least 98-99% sequence identity to SEQ ID NO:2, wherein the sugar concentration is kept at a level below 3 wt % nor a hybrid alpha-amylase comprising an *Aspergillus niger* acid alpha-amylase catalytic domain (CD) and a carbohydrate-binding module (CBM) from *Aspergillus kawachii* alpha-amylase. However, Veit et al. discloses that the preferred

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glucoamylase is of any fungal origin (Column 11, lines 38-67 of US 7,244,597 or page 14 of WO 02/38787 A2). Veit et al. also discloses that various hybrid alpha-amylases were known in the art (page 10 of WO 02/38787 A2), such as Svendsen et al. (WO 96/23874 – form PTO-892).

Svendsen et al. (WO 96/23874 – form PTO-892) discloses a method designing alpha-amylase hybrids comprising of two different acid alpha-amylases, such as an *A. niger* acid alpha-amylase. Many fungal acid alpha-amylases, including the alpha-amylase from *A. kawachii* (Kaneko et al. *J. of Fermentation & Bioengineering*, Vol. 81, No. 4, 292-298, 1996 – form PTO-892) were available to one having ordinary skill in the art.

Nagasaka et al. (Appl Microbiol Biotechnol. 1995 Dec;44(3-4):451-8 – form PTO-892) discloses a method of producing ethanol from milled starch-containing material obtained from whole grain by simultaneous saccharification and fermentation, wherein said starch-containing material is saccharified with a fungal glucoamylase having at least 98-99% sequence identity to SEQ ID NO:2 and the sugar concentration is kept at a level below 3 wt % (page 451, 453 and Figure 2 on page 454). The glucoamylase used by Nagasaka et al. is isolated from *Corticium rolfsii*, which is a synonym for *Athelia rolfsii*, as discussed above. Nagasaka et al. teaches the cDNA encoding the above glucoamylase and that the enzyme has a high degree of starch degrading activity compared to other glucoamylases ((page 451 and Figure 2 on page 454). Claims 35-40, 42-44, and 50-51 are drawn to a method of producing ethanol from milled starch-containing material obtained from whole grain by simultaneous saccharification and

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fermentation, wherein said starch-containing material is saccharified with a glucoamylase having at least 70-97% sequence identity to SEQ ID NO:2 and derived from *Athelia rolfsii* at a temperature below the gelatinization temperature of said starch-containing material and the sugar concentration is kept at a level below 3 wt %.

Therefore, combining the teachings of Veit et al., Svendsen et al., Nagasaka et al., it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use the glucoamylase of Nagasaka et al. and hybrid alpha amylases, such as *Aspergillus niger* acid alpha-amylase catalytic domain (CD) and a carbohydrate-binding module (CBM) from *Aspergillus kawachii* alpha-amylase, in the method of Veit et al. One of ordinary skill in the art at the time the invention was made would have been motivated to use the glucoamylase of Nagasaka et al. since the glucoamylase of Nagasaka et al. is of fungal origin, gene encoding the enzyme of Nagasaka et al. is disclosed and said enzyme can be produced in large, highly-purified quantities, and the glucoamylase of Nagasaka et al. has a high starch degrading activity compared to other glucoamylases. One of ordinary skill in the art at the time the invention was made would have been motivated to use other hybrid alpha-amylases in order to optimize production of the fermentation product.

One of ordinary skill in the art would have had a reasonable expectation of success since Veit et al. teaches a method of producing and recovering ethanol by liquefying a milled starch using a hybrid alpha-amylase, simultaneous saccharification and fermentation with a fungal glucoamylase and a fermenting microorganism,



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Svendsen et al. discloses making various hybrids using known alpha-amylases, and Nagasaka et al. discloses a fungal glucoamylase and cDNA encoding said protein.

Therefore, the above references render claims 52-53 and 55-63 *prima facie* obvious.

### ***Double Patenting***

In view of the cancellation of claims 35-40, 42, 47, and 49-51, the rejection of claims 35-40, 42, 47, and 49-51 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U. S. Patent No. 7,129,069 and US Patent No. 7,312,055, has been **withdrawn**.

### ***Conclusion***

Claim 52-53 and 55-63 are rejected.

### ***Allowable Subject Matter***

Claim 54 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Yong D Pak/  
Primary Examiner, Art Unit 1652